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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,757	01/03/2007	Emma Kvitnitsky	KVITNITSKY1A	5965
1444 7590 10/22/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER CHANDRAKUMAR, NIZAL S	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 10/22/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,757	<b>Applicant(s)</b> KVITNITSKY ET AL.	
	<b>Examiner</b> NIZAL S. CHANDRAKUMAR	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-31 is/are pending in the application.
- 4a) Of the above claim(s) 15-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/2005, 09/26/2008</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, compounds and composition of formula I wherein R3 and R4 are independently H, in the reply filed on 09/22/2008 is acknowledged. The traversal is on the ground(s) that no problem of unity of invention was identified by ISA/US and further lack of unity of invention has not been established by the PTO, and was not even alleged during the international stage, and there is common subject matter among the claims which conforms to the requirements of PCT rules 13.1 and 13.2. This is not found persuasive because of reasons of record. The holding of unity or lack of unity of invention by the international authority is not binding at the US national stage. If at the US national stage a lack of unity can be supported, then lack of unity can be imposed. The invariant structural unit present in the formula (I) is not a contribution over the prior art since ascorbic acid is well known in the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-31 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/22/2008.

Claims 1-5 and 7-14 are examined to the extent that they read on the elected group of compounds.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-14 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the relevant factual considerations.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art.

All of the factors have been considered with regard to the claims, with the most relevant factors discussed below:

Lack of enablement with respect to variable R3 and R4:

The claims are drawn to variables R3 and R4 that are independently H.

The specification discloses compounds in which R3 and R4 are either simultaneously protected as isopropylidene ketal or R3 and R4 are both simultaneously H. There is no guidance, direction or working example for making compounds wherein R3 is H and R4 is anything other than H. The specification does not disclose any prior art citation in lieu of enabling disclosure for obtaining such compounds.

Lack of enablement with respect to variable R2:

The claims are drawn to compounds of formula I wherein R2 is ammonium or a metal cation. Step 4 of working Examples 1 and 2 allegedly describe the synthesis of sodium salt of 2-caryloyl and 2-plamitoyl ascorbic acid starting from the product of the step 3 which describes the basification of 5,6-isopropylidene ascorbic acid with sodium carbonate thus enabling the formation of R2 sodium cation, that is compound of formula I wherein R3 and R4 are protected as isopropylidene ketal. The described reaction in step 4 involves treatment of the product of step 3 with methanolic aqueous HCl and washing with sodium chloride up to pH7. The treatment of an isopropylidene compound with aqueous HCl acid is known in the art to deprotect the hydroxy groups leading to the formation of R3 and R4 H. However, acid treatment of the sodium salt (R2=Na) of an organic acid is expected to result in the neutralization of the salt resulting in the formation of R2 = H. Even though the specification discloses that the product is washed

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with sodium chloride to pH 7, it is art recognized fact that washing of organic acids (R2 =H) with sodium chloride can not lead to salt formation. The specification does not provide any analytical data that would support the formation of sodium salt in step 4. Likewise, there is no teaching in the specification on how to make aminoacid ester derivatives attachment, except for the generic statement that the amino group is protected prior to esterification. Further, with respect to use aspect of the enablement requirement, the disclosure in the specification is limited to speculation that the compounds are expected to be better than ascorbic acid. No data is present. Undue experimentation would be needed to make compounds of formula I wherein R2 is ammonium or any other cation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (EP 0619313 A1).

Shimizu et al., teach page 2 lines 29 to page 3, line 9, page 6 line 24 to page 7 line 3 and Example 1, compounds of the instant formula wherein R2 is lithium.

The difference is that the instant compounds are salts of many other metals except lithium. Further, Shimizu et al. do not teach all the possibilities for R1 as instantly claimed.

One of ordinary skill in the art would be motivated to make alternate salt forms prior art compounds replacing lithium ion with other cations because it is well known in the art that the therapeutic and cosmetic properties (drug effects) of the compounds of ascorbic acid derivatives depend on the ascorbic acid portion of the formulae and the knowledge that the cation portions allows for optimization of physical and chemical properties such as solubility, stability etc. The instantly claimed compounds would have been suggested.

Claims 1-5, 7-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Strelchler et al. (US 6143906).

Strelchler et al. teach in claim 1 (column 11) ascorbic acid derivatives corresponding to compounds of the instant formula I wherein R3 and R4 of the instant

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case corresponds to R1 and R2 of prior art; R2 of the instant case corresponds to R3 of prior art; R1 of the instant case corresponds to C6 acyl group of the prior art.

Strelchler et al. do not teach all possibilities of the R1 variable. Strelchler et al.s compounds are limited to 2-sorbyl, that is C6-acyl derivatives, while the instant compounds are C8-C18 acyl derivatives. (Further, Strelchler et al. do not teach R1-alkyl (that is 2-alkoxy) compounds of the instant formula I; see above, Shimizu et al., teach lithium salts of alkoxy compounds).

One of ordinary skill in the art would be motivated to make alternate forms of compounds of Strelchler et al. by replacing the C6 2-acyl substitutions because the alkyl homologs are suggestive of each other. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new compounds. A strong case of prima facie obviousness has been established.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625